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Sent: 4/20/2011 10:49:47 PM
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Subject: Internal Audit Report-Confidential

I have attached the Distribution Center Audit just completed by Internal Audit. I share this with you as I have done in the past so that you have a detailed view of what audit found. The three major areas centered around 1)Secondary wholesalers and pedigree 2) Licensing and 3) Consistently following SOP's including documentation. As you read through it I think you will agree we have work to do, we need to collectively and collaboratively step up our reinforcement of following SOP's and completing various compliance tasks as outlined in MOM. The secondary and licensing issues are being worked on.

Actions:

1) DRA's review the issues log and be prepared to discuss at our upcoming staff call
2) VPDO's give me some feedback on how we can improve this profile in the DC's

I am certain that if we picked four different DC's we would find the same issues so we should assume this is a network wide concern.

Please do not distribute this document beyond this group. You can summarize for any region DCM calls but in fairness to the inspected DC's we do not want to share the DC specific details.

This audit will repeat again next year with four different DC's and we do not want or need any repeat comments.

Don

Audit Report

Distribution Center Audit

US Pharmaceutical Distribution Operations

To:	Don Walker, Senior Vice President, Distribution Operations
From:	Internal Audit Department
Subject:	US Pharmaceutical Distribution Center Audit

	Current Audit	**Prior Audit**
Date Audit Completed:	March 14, 2011	April 9, 2010
Audit Report Date:	April 20, 2011	July 20, 2010
Report Reference Number:	11-SSPH-08	10-SSPH-11
Rating:	Yellow – Needs Improvement	Yellow – Needs Improvement
Copies To:	See Distribution List	

Approved By:

Mark Fuller
Vice President, Internal Audit

Distribution

Jeff Campbell	Executive Summary
John Hammergren	Executive Summary
Paul Julian	Executive Summary
Laureen Seeger	Executive Summary
Frank Starn	Executive Summary
Brian Tyler	Executive Summary
Alain Vachon	Executive Summary
Ed Vianco	Executive Summary
Patrick Broderick	
Kevin Heck	
Tracy Jonas	
Nigel Rees	
Bruce Russell	
Deloitte	

Executive Summary

Background

McKesson US Pharmaceutical (US Pharma) focuses on distributing branded, generic, and over-the-counter pharmaceuticals to more than 40,000 customers spanning retail national accounts, independent retail pharmacies and institutional providers such as hospitals, health systems, integrated delivery networks, and long-term care providers. In fiscal year 2010, revenues for McKesson were $109 billion with EBIT of $2 billion. The US Pharmaceutical business accounted for 82% ($89 billion) of McKesson's FY10 total revenues and 75% ($1.5 billion) of total EBIT. Fiscal year 2011 forecasted revenues for the US Pharmaceutical business is $90 billion with $1.7 billion EBIT.

US Pharma Distribution Operations utilizes the US Pharma Standard Team Audit Review System (STARS) to assist in complying with applicable operational, financial, and regulatory compliance requirements and objectives. The STARS program consists of various sections that address inventory, security, operational, and regulatory risk areas. Resources have been assigned to oversee the STARS program in order to coordinate the audits in these specialized areas and ensure compliance with Standard Operation Procedures and applicable regulatory requirements. In addition, a STARS Audit Review Committee (SARC) has been established for the ongoing maintenance and overall governance of the STARS program, which includes key stakeholders from a variety of dedicated business functions.

The Food, Drug, and Cosmetic Act and regulations established by the Food and Drug Administration (FDA) requires wholesale distributors who engage in the wholesale distribution of prescription drugs in interstate commerce to be licensed by the state licensing authority. In addition, any entity who manufacturers, distributes, dispenses, imports or exports controlled substances is required to obtain a federal Drug Enforcement Administration (DEA) registration and in many cases a separate state license for the activity performed related to controlled substances. Separate registrations are required for each principal place of business or physical location where controlled substances are distributed. Due to the strict licensing requirements for prescription and controlled substance products, McKesson has established enhanced procedures and associated controls to monitor licensing requirements for the distribution of these products.

Various levels of government agencies, including state boards of pharmacy, have increased efforts to regulate the pharmaceutical distribution system to prevent introduction of counterfeit, adulterated, and/or mislabeled drugs into the distribution channel. The federal Prescription Drug Marketing Act (PDMA) requiring pedigree and chain of custody tracking was enacted on April 12, 1988, and in December 2006 the FDA established regulations expanding the drug pedigree requirements. In addition, approximately twenty-nine states have adopted, implemented, or proposed rules and regulations to create state pedigree requirements that are intended to protect the integrity of the pharmaceutical distribution system. US Pharma is in the process of improving current Standard Operating Procedures (SOP) to address both federal PDMA and state pedigree requirements. These updated SOP's will include protocols for monitoring wholesale licensed customers, prescription drug ordering, receiving, stocking, order filling, and the return of pedigree products.

Failure to comply with FDA, DEA or state regulatory requirements could result in administrative, civil or criminal enforcement actions such as license restrictions, license revocation, or monetary penalties.

Scope and Objectives

As part of Internal Audit's fiscal year 2011 (FY11) Audit Plan, we performed an audit of the processes and procedures related to US Pharma Distribution Operations leveraging the STARS Program. Our audit focused on evaluating the effectiveness and efficiency of selected operational policies and procedures; and verifying that adequate controls exist to ensure the accuracy, completeness, and reliability of financial information. Our audit covered the period from June 1, 2010, through January 30, 2011. Internal Audit reviewed processes and performed testing at US Pharma Distribution Centers located in Delran, NJ; New Castle, PA; Washington Court House, OH; and Conroe, TX.

Our primary audit objectives were as follows:

- Assess the effectiveness and governance of the STARS Program
- Evaluate Distribution Center financial and operational controls leveraging selected STARS Program workbooks:
  - Inventory Management
  - Security
  - Regulatory Drug Enforcement Administration
  - Regulatory Hazardous Materials
  - Regulatory Food and Drug Administration
- Assess the effectiveness of key controls associated with applicable DEA, state Board of Pharmacy, and other authority's licensing requirements
- Evaluate the effectiveness of controls related to applicable pedigree requirements

Overall Conclusion

Yellow – Needs Improvement

Based on the testing performed to meet our audit objectives, we concluded that controls related to regulatory compliance, operations, and system access need to be strengthened and enhanced. While the US Pharma Distribution network maintains a robust control environment and stringent Standard Operating Procedures (SOP's), overall results of the audit indicate that the Distribution Centers are not consistently completing and maintaining the required documentation associated with certain SOP's. Operational controls associated with pedigree requirements are not strictly enforced to ensure full compliance with PDMA and state regulations. In addition, controls related to FDA and state license monitoring are not operating effectively. The STARS Audit Review Committee (SARC) will collaborate with Regulatory Affairs to continue to educate Distribution Center management on regulatory requirements and work towards the implementation of pedigree control testing in the STARS workbooks to ensure compliance with applicable regulations.

A detailed report of all issues has been provided to the appropriate management and is available upon request.

Key Issues

Pedigree Requirements

Although McKesson facilities are generally not required to provide a pedigree when acting in a capacity as an Authorized Distributor of Record (ADR) or when they distribute products within the normal chain of distribution, the Prescription Drug Marketing Act (PDMA) requires a secondary wholesale distributor (i.e. a non-ADR) to establish pedigree from the manufacturer or the last ADR. In addition, certain states have established more stringent pedigree requirements if a drug product is distributed outside the normal chain of distribution. Consequently, in some cases a manufacturer's ADR, like McKesson, may have to establish drug pedigree information when the product is shipped to a secondary wholesale distributor or outside the normal chain of distribution. McKesson is in the process of implementing a Standard Operation Procedure (SOP) which states that shipments to customers with wholesale licenses (secondary wholesale distributors) will be performed by the Washington Court House or Lakeland Distribution Centers in order to ensure the required pedigree is included during invoicing.

During our review of controls related to pedigree requirements, we noted that there is not a control in place to track or monitor wholesale licensed customers (or secondary distributors) to ensure these customers are serviced out of a full pedigree servicing Distribution Center and the required pedigree is included during the invoicing process. In an attempt to implement an internal control to monitor wholesale licensed customers, the DC network has internally classified some wholesale license customers as type 21 within SAP; however, this process has not been formally defined, approved or implemented. In addition, the type 21 customer is not consistently used for only wholesale licensed customers and a periodic review to ensure the classification of customers is accurate and solely applies to wholesale licensed customers is not in place. Distribution Operations management has made progress

to obtain approval from business stakeholders on a formalized monitoring mechanism, which is expected to be implemented in early fiscal year 2012.

Based on our findings at the four distribution centers reviewed, it is likely this issue may reside at additional locations throughout the Distribution Center network. In addition, this issue is a repeat finding from the fiscal year 2010 US Pharma Distribution Center Internal Audit.

Management Action Plan

Regulatory Affairs will communicate Pedigree requirements to Distribution Center management teams and the Pedigree SOP will be updated to clearly state the requirements for both full service pedigree Distribution Centers as well as those Distribution Centers not setup for this service. The STARS Audit Review Committee (SARC) will work to create and implement testing related to Pedigree controls to ensure compliance with applicable Pedigree requirements.

In addition, a control will be implemented and associated SOP created by Distribution Operations instructing Distribution Center management to review all type 21 customers on a monthly basis to determine whether the customers are appropriately categorized as type 21 and whether they are required to be serviced out of a specified full service pedigree Distribution Center.

Audit Committee Summary

US Pharmaceutical Distribution Operations utilizes a monitoring function within its Distribution Center network called the Standard Team Audit Review System (STARS) to self-audit risks associated with inventory, security, operations, and regulatory requirements. Our audit focused on a review of Distribution Center operational and financial controls leveraging the STARS program. In addition, we evaluated the effectiveness of key controls related to pedigree and licensing requirements.

Overall audit results indicate the STARS Program is operating as intended and meeting the objectives of the stakeholders. However, during our review of selected Distribution Centers we noted that adequate controls are not in place to ensure the required pedigree is included when invoicing applicable customers. Also, required documentation associated with Standard Operating Procedures was not consistently completed and retained. We also noted certain controls related to DEA, FDA and state license monitoring are not operating consistently.

These issues, along with opportunities for improvement, have been communicated to the appropriate level of management, and action plans have been created to address these areas across the DC network.

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
1	**Pedigree Controls** During our review of controls related to pedigree requirements, we noted that there is not a control in place to track or monitor wholesale licensed customers (or secondary distributors) to ensure these customers are serviced out of a full pedigree servicing Distribution Center (DC) and the required pedigree is included during the invoicing process. In an attempt to implement an internal control to monitor wholesale licensed customers, the DC network has internally classified some wholesale license customers as type 21 within SAP; however, this process has not been formally defined, approved or implemented. In addition, the type 21 customer is not consistently used for only wholesale licensed customers and a periodic review to ensure the classification of customers is accurate and solely applies to wholesale licensed customers is not in place. Based on our findings at the four distribution centers reviewed, it is likely this issue may reside at additional locations throughout the Distribution Center network. In addition, this issue is a repeat finding from the fiscal year 2010 US Pharma Distribution Center Internal Audit.	Significance: High Risk: Product may be shipped to a secondary wholesaler without a pedigree included in the invoice, which could result in non-compliance with state or federal regulations.	Recommendation: Regulatory Affairs should communicate Pedigree requirements to DC management teams and the Pedigree SOP should be updated to clearly state the requirements for both full service pedigree DCs as well as those DCs not setup for this service. The STARS Audit Review Committee (SARC) should work to create and implement testing related to Pedigree controls to ensure compliance with applicable Pedigree requirements. In addition, a control should be implemented and associated SOP created by Distribution Operations management instructing DC management to review all type 21customers on a monthly basis to determine whether the customers are appropriately categorized as type 21 and whether they are required to be serviced out of a specified full service pedigree DC. DC management should review all type 21 customers to determine if these customers are secondary distributors. The customers that are deemed as secondary distributors should be serviced out of Washington Court House, and the remaining customers should be properly coded in the system.	**Bruce Russell/ Tracy Jonas**	June 30, 2011
2	**Accuracy of DEA Registration and State License Expiration** The McKesson Operations Manual (MOM) (Reference MOM-CTRL-008), in accordance with DEA regulation section CFR 1301.74(a), notes that the distributor is responsible not only for the initial verification of registration prior to the first shipment of controlled substances to a registrant, but also for the periodic monitoring of the status/validity of that registration. Based on our review of 10 customer DEA and state licenses entered into DCUS at the Conroe distribution center, Internal Audit noted the expiration date for one	Significance: Moderate Risk: If registration or license expiration dates are inaccurately entered into DCUS, the DC may ship pharmaceutical products to customers with expired registrations or licenses.	Distribution Center management will implement a periodic review of customer expiration dates entered into DCUS for accuracy. In addition, the expiration dates for the noted customers have been corrected in the system.	**Mike Fabela**	May 16, 2011

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	DEA registration and one state license was not accurately entered into DCUS. An automated control has been implemented to block orders of controlled substances or Rx product if customer licenses have expired, however the effectiveness of this control is dependent on the accuracy of customer license expiration dates entered into DCUS.				
3	**State Licenses** The McKesson Operations Manual (MOM) (Reference (MOM-SAF-019 and MOM-REG-002) requires that all state licenses will be current and posted in a conspicuous area. A) During our review of state licenses at Delran, New Castle, Washington Court House, and Conroe DC's, we noted the state distribution licenses were not consistently posted in a conspicuous area as follows: ***Delran:*** One state license (Oklahoma) was not posted, however the license was maintained at the DC. ***New Castle***: Thirty-eight state licenses were not posted. The licenses were kept in a binder in the front office. ***Washington Court House:*** Two state licenses (Indiana and Louisiana) were not posted, however the licenses were maintained at the DC. B) In addition, the DC State License spreadsheet maintained by the Regulatory Affairs Specialist did not accurately reflect certain state licenses maintained at DCs selected for testing. The license number and/or license expiration date listed on the spreadsheet did not match to the posted license at the DC as follows: ***Delran:*** Michigan state license numbers and expiration dates were incorrectly listed on the spreadsheet. In addition, the New Jersey pharmacy license permit, mercantile (a New Jersey required license) license, and state DEA licenses were not included on the	Significance: Moderate Risk: Required state licenses may not be effectively monitored or adequately posted, resulting in failure to timely renew or maintain current state licenses.	Distribution Center management will ensure all state licenses are properly posted in a conspicuous area. Distribution Center management and the Regulatory Affairs Specialist will coordinate efforts and assign an individual at the DC who is responsible for obtaining and reviewing the DC State License spreadsheet on a monthly basis. This review will be documented and retained.	**Tracy Jonas** **Tracy Jonas/ Cynthia Branch**	May 16, 2011 May 31, 2011

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	spreadsheet. *New Castle*: The state license numbers and expiration dates for 6 states (District of Columbia, Hawaii, Michigan, New Jersey, Ohio, and South Carolina) were incorrectly recorded to the spreadsheet. *Washington Court House*: The state license numbers and expiration dates for 10 states (Arkansas, California, Georgia, Hawaii, Idaho, Louisiana, New Jersey, New Mexico, New York, and North Carolina) were incorrectly recorded to the spreadsheet. *Conroe*: The Texas DEA and wholesale distribution licenses were not recorded to the spreadsheet.				
4	**Licenses with 12/31/2099 Expiration Date** The McKesson Operations Manual (MOM) (Reference MOM-REG-003) requires that customer license reports be generated to identify customer accounts that do not have a valid license and/or valid expiration dates. The policy stipulates that the report will be printed, reviewed, signed, dated by distribution center management and retained for a 12 month rolling basis. During our review, Internal Audit noted the Delran, New Castle, Washington Court House, and Conroe DC's are not printing, reviewing, and retaining the required reports listing customers in the system without license expiration dates or licenses expiring on 12/31/2099, which is the system generated date for customers with indefinite license expiration dates. In reviewing the customer license reports we noted no instances in which a customer had an invalid or expired license.	Significance: Moderate Risk: License information may not be appropriately recorded in the system, which could result in product shipped to customers with invalid or expired licenses.	DC management will print, review, sign-off and retain the required reports on a monthly basis to ensure that appropriate action is being taken for those customers with indefinite expiration dates recorded in the system.	**Tracy Jonas**	May 31, 2011
5	**Reclamation** The McKesson Operations Manual (MOM) (Reference MOM-RCL-001) states that on a monthly basis, the DC performs a "reclamation unit validation" (RUV) of the all the unsalable products boxed within the reclamation area to confirm that all reclamation units (or boxes) are listed and present in reclamation. Access to the reclamation	Significance: Moderate Risk: Access to the Reclamation area may not be properly secured which could result in loss or theft of product.			

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	area is limited to authorized personnel and secured during breaks, lunches and at close of day. During a physical observation of the reclamation area, we noted the following: *Conroe* A) There was one unit listed in the warehouse management system (Acumax) as located in the reclamation area that did not exist and could not be located. B) Five large openings alongside the fenced area of the reclamation cage facing the receiving dock were not properly secured and allowed for easy access to product located within the reclamation area. *New Castle* During a walkthrough of the reclamation area Internal Audit was able to lift the Reclamation gate off the locking mechanism to open the gate and gain full access to the reclamation area.		*Conroe* DC Management will ensure product located within the reclamation area is secure and correctly captured during the reclamation unit validation process. *New Castle* Management placed a rail above the gate which no longer allows the gate to be lifted off the locking mechanism.	**Mike Fabela** **Blain Snider**	May 16, 2011 Completed
6	**IAID Access** The McKesson Operations Manual (MOM) (Reference MOM-INV-ADJ-001) states that during the first month of every quarter the Computer Room Supervisor (CRS) runs the USERSIAID query to print out the IAID system access listing from Acumax. The DC Manager (DCM) and CRS are required to verify the appropriateness of all users that have IAID access, and the report is signed off and maintained for a rolling 12 month period. The quarterly USERIAID report selected for review at the Conroe DC was signed by the Assistant Distribution Center Manager (ADCM). The report should be signed by the Director of Operations (DO) since the distribution center does not have a DCM. The DO was signing the report on a quarterly basis but was signing the report the last month of the quarter instead of the required first month of the quarter. In addition, there were two members of the DC management staff that were inappropriately listed on the USERIAID report.	Significance: Moderate Risk: Inappropriate access to IAID could result in inappropriate adjustments to inventory, resulting in potential misstated financials or financial loss to McKesson.	The DC Director of Operations will perform a detailed review and sign the USERIAID report the first month of every quarter and ensure the appropriate individuals have access to IAID.	**Mike Fabela**	May 31, 2011

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
7	**Returns** Per the McKesson Operations Manual (MOM) (Reference MOM-SAF-019) customer Return Authorizations are required to be signed by the customer acknowledging the product has been stored based on manufacturer specifications and the integrity of the product is still intact. If the customer has not signed the authorization form, the product should be refused. During our review of Return Authorizations, we noted the following: ***New Castle*** Ten of the 25 hospital Return Authorizations selected did not have a customer signed and dated Prescription Drug Marketing Act (PDMA) storage requirement statement on file. ***Washington Court House*** Four out of 25 hospital Return Authorizations (RAs) selected for testing from September to December 2010 did not include the customer signature and date certifying the PDMA statement. ***Conroe*** Three out of 25 Return Authorizations (RAs) selected for testing from September to December 2010 did not include the customer signature and date certifying the Prescription Drug Marketing Act (PDMA) statement.	Significance: Moderate Risk: Without a PDMA statement certification, McKesson has no assurance the product was handled and stored appropriately while it was in the customer's possession, which could impact the integrity of the product.	Customer signatures and dates for the PDMA statement on Return Authorizations (RAs) will be closely monitored. Management will implement a daily double check process for RA's received to ensure that the PDMA statements are being completed by the customer.	**Tracy Jonas**	May 31, 2011
8	**DEA Form 41** Per the Tri-annual Checklist (reference MOM-CTRL-001) the DEA Form 41 (which is a monthly reporting of all controlled drugs destroyed at the distribution center) should be properly completed and submitted to the DEA on a monthly basis with a copy retained in the DC's appropriate month's records. The December 2010 DEA form 41 was not signed by New Castle DC management and the form included the destruction of controlled substances from October and November 2010.	Significance: Moderate Risk: Notification of the destruction of controlled substances is not transmitted in the appropriate month to the DEA, which could result in the failure to comply with DEA reporting requirements.	DC management will ensure all DEA Form 41's are signed and transmitted in the month in which controlled substance destructions occur.	**Blaine Snider**	May 31, 2011

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
9	**DEA Background Checks** Per the DEA Tri-annual Checklist (Reference MOM-CTRL-001) the DC should perform new hire employee DEA background checks prior to granting employee access to enter the cage or vault. In addition, annual employee background checks should be performed for those who have access to the cage or vault. Documentation was not on file to support that a DEA background check was performed for all ten employees selected for testing with cage and vault access at the New Castle DC.	Significance: Moderate Risk: Failure to perform or maintain support for the required DEA background checks may result in inappropriate authorization of access for individuals to controlled substance storage areas.	Distribution Center management will ensure that the required criminal background checks are performed for all employees with cage and vault access. Documentation to support these background checks will be retained and readily available.	**Blaine Snider**	May 16, 2011
10	**Level One Forms** Per McKesson Operations Manual (MOM) (Reference MOM-CTRL-007) between the third and eighth work day of the new month, the DC will be provided a report that will identify controlled substance orders omitted during the previous month. The DC is required to validate that all omitted items listed on the report for customers exceeding their controlled substance threshold has an associated Level One form completed. In addition, the DCM or designated manager will sign, date and retain the report and Level One forms in the CSMP file. Based on our review of the controlled substance omit reports, we noted the following: ***Delran*** The omit reports were not being signed by DC management as required by policy. In addition, the required Level One forms were not completed for 20 of the 56 omits in July 2010, and all 54 omits for the month of November 2010 ***New Castle*** The omit reports were not being signed by DC management as required by policy. In addition, the required Level One forms were not completed for 21 of the 30 omits in July 2010, and 20 of the 27 omits in November 2010. ***Washington Court House*** The required Level One forms were not completed for all 19 omits in July 2010, and all 11 omits in November	Significance: Moderate Risk: Failure to follow procedures for documenting controlled substance order omit forms could compromise effective monitoring of suspicious orders as required by DEA regulations.	The DC will ensure that the required Level One forms are completed for all controlled substance orders omitted due to customers exceeding their thresholds (V-code omits). In addition, the omit summary reports will be signed and retained by DC management on a monthly basis.	**Tracy Jonas**	May 31, 2011

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	2010. In addition, the omit report was not signed and dated by DC management as required by the policy. ***Conroe*** The omit reports were not signed and dated by management as required by policy. In addition, Level One forms were not completed for the July and November 2010 omits. CSMP Excursion contract forms were used in place of the Level One forms, although 22 of 35 omits in July, and 17 out of 35 omits in November didn't have any completed documentation.				
11	**Threshold Change Requests** Per the MOM (Reference MOM-CTRL-007), the DC is required to perform a review of the monthly Threshold Change and Omit Reports to monitor customer orders and purchases of DEA controlled substances. Distribution Center Manager (DCM) or designated manager will sign, date and retain the required documentation in the CSMP file. During our review of controlled substance threshold changes, we noted the following: ***Delran*** Based on our review of 103 Threshold Change Request forms (TCR) for July and November 2010, we noted 38 out of 66 forms were not on file for the month of November. In addition, DC management did not sign and date the Threshold Adjustment report for July and November 2010 as required by the policy. ***New Castle*** One Threshold Change Request form was not on file to support a change in a customer's controlled substance threshold. In addition, one of the TCRs reviewed did not contain the required information (e.g., base code, increase amount, increase reason, etc.). ***Washington Court House*** Based on our review of the Threshold Change Request forms for July and November 2010, we noted that 7 forms were not on file at the DC. In addition, the Threshold Adjustment report was not signed and dated by DC management for July and November 2010 as required by the policy.	Significance: Moderate Risk: Failure to follow established controlled substance customer monitoring procedures could impact the effectiveness of the DEA required suspicious order monitoring system.	DC management will ensure that Threshold Change Request forms are on file for all threshold adjustments that occur. In addition, the Threshold Adjustment report will be reviewed and signed by DC management on a monthly basis.	**Tracy Jonas**	May 16, 2011

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	Conroe Two Threshold Change Request Forms for July and November 2010 were not on file at the DC. In addition, the Threshold Adjustment report was not signed and dated by DC management for July and November 2010 as required by the policy.				
12	**Temperature Monitoring** Per the McKesson Operations Manual (MOM) (Reference MOM-SAF-019), product requiring refrigeration storage must be maintained in an environment with a temperature between 36 and 46 degrees Fahrenheit. These temperatures must be monitored based on PDMA guidelines. We noted the following during our review of DC temperature monitoring: ***Delran:*** Four refrigeration temperature monitors recorded spikes outside the acceptable temperature range. In addition, a temperature log is not maintained for a back-up refrigeration unit located in the back-up cage. The unit is occasionally used to store inventory-overflow. ***New Castle:*** One refrigeration temperature monitor recorded spikes outside the acceptable temperature range. ***Washington Court House:*** Five refrigeration temperature monitors recorded spikes outside the acceptable temperature range, while two refrigeration temperature monitors did not consistently record temperatures. In addition, we noted that there is no documented corrective action plan for temperature excursions on the temperature monitoring reports.	Significance: Moderate Risk: Inventory may spoil and could become unsalable if the required temperatures are not maintained.	***Delran*** Management will installed a mechanism to alert the warehouse if the bio box door is left opened after a certain amount of time. Management will complete a temperature log for refrigeration units that are not monitored by Enako. ***New Castle*** Management will ensure temperature monitors are regularly monitored and any spikes are investigated and remediated. The inappropriate temperature deviations were investigated and it was deemed that none of the product was compromised as the temperature deviations noted were minimal. ***Washington Court House*** Management will ensure temperature monitors are regularly monitored and any spikes will be investigated and remediated. The inappropriate temperature deviations were investigated and it was deemed that none of the product was compromised as the temperature deviations noted were minimal.	**Daniel Montreuil** **Blaine Snider** **Kevin Meunier**	May 16, 2011 May 16, 2011 May 16, 2011

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	Conroe: One refrigeration temperature monitor recorded spikes outside the acceptable temperature range on eight different occasions. We also noted one refrigeration temperature monitor did not record the temperature on 11/30/10. Internal Audit also reviewed the monitoring reports to ensure the warehouse was monitored and consistently maintaining temperatures between 59 to 86 degrees, and a mean kinetic temperature below 77 degrees. During our review, we noted one warehouse temperature monitor did not consistently report a temperature for multiple days during the months of September, October, and November 2010.		***Conroe*** Management will ensure temperature monitors are regularly monitored and any spikes will be investigated. The inappropriate temperature deviations were investigated and it was deemed that none of the product was compromised as the temperature deviations noted were minimal. Management noted the temperature fluctuations occurred during receiving hours and were due to the frequent and long-periods of time the refrigerator door was left opened. Management also noted the warehouse monitor was sending a weak signal. The monitor has been evaluated and fixed.	**Mike Fabela**	May 16, 2011
13	**Controlled Substance Inventory Count** Per the McKesson Operations Manual (MOM) (Reference MOM-CTRL-001) any inventory discrepancies of controlled substances that appeared on the semi-annual physical "Count Audit" report should be resolved and explained. During our review of DC count books we noted the following: ***Washington Court House*** A) A computer generated report for the second count discrepancy testing was completed instead of the required notations made on the second count book of the Semi Annual count. Since the second count discrepancy was not manually filled out, there is no evidence to suggest that physical counting occurred. B) Six out of 20 samples selected showed discrepancies between the first count and second count without explanations. C) Three consolidated count books did not contain the time of day with the approval as required per the checklist.	Significance: Moderate Risk: Controlled Substance Count books may not be properly completed, which could result in failure to maintain accurate controlled substance inventory records as required by state and DEA regulations.	DC Management will review the SOP with the ARCOS department and implement processes to ensure all count books are completed and signed/dated/time stamped. This will ensure that all consolidated ARCOS count books contain the DCM's signature and the required text (date and time of day) to ensure policy compliance.	**Tracy Jonas**	May 16, 2011

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	Conroe A) Count books were not signed, dated and time of the day noted by DCM or designated manager. B) The biennial book does not have the specific language "Biennial Inventory" physically written on the book. C) Three unresolved discrepancies were noted between the first and second count of Semi-Annual inventory with no explanation. D) A few modifications were made in the count books without explanations.				
14	**Durable Medical Equipment (DME) Accounts** Per the McKesson Operations Manual (MOM) (Reference MOM-REG-003) durable medical equipment (DME) accounts are not required to obtain a license to purchase durable medical equipment. However, the DC is responsible for monitoring to ensure that no prescription (Rx) items are ordered by these accounts, since the DME set-up will permit purchases of all Rx items. *New Castle* Based on our review of the purchase history for the DC's DME accounts, Internal Audit identified one DME account that purchased an Rx item on auto-ship. The DC indicated that the item was likely returned to the customer's master account, which has a state license on file to purchase Rx goods; however, no documentation to support this could be provided. *Washington Court House* Based on our review of purchase history for the DC's DME accounts, Internal Audit identified one of five DME accounts that purchased non-DME Rx items without a valid state license on file. Upon review of the order history, Internal Audit identified 14 invoices containing non-DME Rx product.	Significance: Moderate Risk: Failure to adequately monitor product shipments to DME accounts may result in unauthorized prescription products inappropriately shipped to DME customers without a valid license.	The DC will ensure that orders for all DME accounts are adequately monitored to prevent shipment of Rx items to DME accounts.	**Tracy Jonas**	May 16, 2011
15	**Methadone Customer Listings and WF415R01 Report** The McKesson Operations Manual (MOM) (Reference MOM-REG-DEA-031) requires that a list of all	Significance: Moderate Risk: Customers may not be appropriately classified as			

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	authorized purchasers of the effected methadone (schedule II drug) be posted in the vault. During our review, we noted the following: ***Delran*** Two customers were inappropriately identified as methadone customers on the vault methadone customer listing. In addition, two methadone customers were not listed on the WF415R01 report (which identifies customers that are limited to ordering only select schedules II through V products), as they were inappropriately setup in AS400 with the ability to order all controlled substances.	methadone only customers within the system, which could result in the shipment of other controlled substances to the customer.	***Delran*** The DC will update the methadone listing to include the appropriate customers, and AS400 will be updated to reflect that the methadone accounts receive only schedule two drugs. In addition, management will work with the Directors of Regulatory Affairs to implement a periodic review of the methadone customer listing and the WF415R01 report for accuracy.	**Daniel Montreuil**	May 31, 2011
16	**Visitors and Access Badge Logs** The McKesson Operations Manual (MOM) (Reference MOM-SEC-002) requires management to control and maintain a log of visitor "Access Badges" (badges that allow access to warehouse and/or other secure areas). All fields of the Visitors' access Badge log will be properly completed, which includes date, signature, printed name, employer, time-in, time-out, badge number and if badge was returned. If not returned, a disposition for the badge/access will be noted and deactivated. Also, all visitors should be escorted while in the warehouse or product storage areas. During our review of the Access Badge and Visitor logs we noted the following: ***New Castle*** The DC is not maintaining a separate Visitor Log and Visitor Access Badge Log. These Logs have been combined into one log, and sufficient information is not recorded to differentiate between a visitor's pass and a visitor's access badge. There are 11 non-McKesson individuals permanently assigned visitor badges. The Central Fill facility employs four non-McKesson pharmacists with authorized badge access to the DC warehouse. These pharmacists have access to enter and exit the DC but are not escorted.	Significance: Moderate Risk: Access to the DC may not be properly monitored, which could result in unauthorized access to McKesson facilities.	***New Castle*** DC management will maintain an access badge log and a separate visitors log and ensure all fields in the log are properly completed. In addition, management will perform a periodic review of these logs to ensure they are being properly completed and any access badges that are not returned are deactivated. All non-McKesson pharmacists will be escorted through the warehouse moving forward. All employees take lunch and breaks at the same time every day, the non-McKesson pharmacists will be required to exit with the McKesson employees at the	**Blaine Snider**	May 16, 2011

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			scheduled break times.		
	Washington Court House All fields were not properly completed on the visitor sign-in log including the signature line, person visiting, company representing and visitor's signature for the months of October and November 2010. One of the 17 visitors reviewed on the Visitor Access Badge log did not complete the signature line on 9/27/2010. *Conroe* A) The access badge log is not being properly completed. There were multiple instances in which the badges' return date was not documented, and the DC employee who authorized the issuance of the badge was not recorded. B) During our review of the DC perimeter, we noted the side entry/exit door leading into the break room foyer was unsecured and unlocked. There were no employees within the vicinity to monitor this area. However, this foyer does not allow access inside the building as there is an additional locked door needed to enter the facility.		*Washington Court House:* Management will perform a periodic review of these logs to ensure they are being properly completed. *Conroe* Continuous education will be completed with all employees responsible for the badge log to ensure all information is properly filled out when badges are issued and returned. The perimeter door will be adjusted to ensure proper closure of outside door.	**Kevin Meunier** **Mike Fabela**	May 16, 2011 May 16, 2011
17	**Drop Zone Reporting** Per the McKesson Operations Manual (MOM) (Reference MOM-PUT-001) any items located in a drop-zone for longer than 48 hours will require a reason and resolution of the problem notated or attached to the DRPZOLD report. The report will be signed, dated and retained for a rolling 12 month period. In addition, on a weekly basis the CRS or their designee will run the Allocated Inventory Report, which lists all items in stock on allocated status but inactive. The report will be signed, dated and retained for a rolling 12 month period. Internal Audit reviewed 25 daily drop-zone reports and noted that 1 daily report had an inventory item that exceeded 48 hours in a drop-zone. The report contained no written reason or resolution of the problem nor did it contain any attachments to the report. In addition, the Allocated Inventory Report was not being reviewed on a	Significance: Low Risk: The lack of required report review increases the likelihood of product maintained in drop-zones for excessive periods, which may result in misplaced inventory.	Management has implemented a process to ensure that the day warehouse leads run the report daily to verify all drop-zones are clear. In addition, the Computer Room Supervisor has the AIR report set to run weekly, in order to be reviewed and signed off.	**Kevin Meunier**	May 16, 2011

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	weekly basis as required per policy.				
18	**Off System Orders** The McKesson Operations Manual (MOM) (Reference MOM-ORD-ENT-001) states the DC manager or their designate compares the off-system order detail to the invoice for all off-system orders on a daily basis. During the review of the off system orders log at Washington Courthouse DC, Internal Audit noted that the log was not properly completed for off system orders on 7/31/2010 through 8/2/2010. The log did not capture sufficient information for three orders including the customer account number, unit number, account name, driver's license number, name, signature, class and evidence of verification.	Significance: Low Risk: Insufficient completion of the off-system order log could result in untraceable release of inventory and potential loss of product.	DC management will review the procedures for completing the off systems orders log with employees to ensure they are current on their responsibilities.	**Kevin Meunier**	May 16, 2011
19	**Business Warehouse (BW) License Report** The McKesson Operations Manual (MOM) (Reference MOM-REG-003) mandates that all expiring customer DEA registrations be tracked and current registrations obtained on a monthly basis. During our review, we noted the following: ***Delran*** The Delran DC is not utilizing the BW License report to monitor the expiration of customers' DEA registrations as required per the policy. However, the distribution center is monitoring expiring customer DEA registrations and obtaining proof of valid registrations with an alternative query. ***Washington Court House*** Based on our review of the BW License queries, we noted that the report was not signed by DC management for the month of December 2010. ***Conroe*** DC management did not sign and date the BW License query for January 2011. In addition, No BW License query reports were available prior to January 2011, and the DR48 report (which preceded the BW License query) was not on file for several months from 2008 through 2010.	Significance: Low Risk Without utilizing the required and approved report to monitor expiring customer DEA registrations, the integrity of the alternate query may not be sufficient and could allow for customers with expiring DEA registrations to go undetected.	DC management will utilize the BW License report to monitor the expiration of customer DEA registrations as required by policy. This report will be signed off as reviewed and retained for a 12 month rolling period.	**Tracy Jonas**	May 16, 2011

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20	**DEA Tri-Annual Checklist Exceptions** The McKesson Operations Manual (MOM) (Reference MOM-CTRL-001) requires DC management to complete a DEA Tri-Annual Checklist to ensure the DC is in compliance with DEA processes. During our review, we noted the following: ***Delran*** Based on our review of three DEA Tri-Annual Checklists, we noted that each checklist contained exceptions related to the completion of ARCOS daily edits reports subsequent to the required 24-hour deadline. A) Two of the three checklists indicated exceptions that the distribution center was completing the ARCOS reporting within 48 hours as opposed to 24 hours. Corrective action had not yet been completed to resolve the delayed submissions. B) One of the three checklists indicated that the ARCOS reporting was not being processed within 24 hours; however, no exception was noted on the checklist. ***New Castle*** A) All three Tri-Annual Checklists reviewed noted that exceptions related to either documentation of the approval on the ARCOS count books or performance of ARCOS second counts by the appropriate individual had not been resolved. B) Based on our re-performance of DEA Tri-Annual Checklist we noted that authorization to store non-controlled substances in the cage was not on file for the following items: Cialis, Levitra, Cipro and Revatio.	Significance: Low Risk: Failure to follow established procedures could result in non-compliance with DEA recordkeeping and reporting requirements.	***Delran*** DC management will implement cross training of personnel to ensure that ARCOS daily edits are completed within the 24-hour requirement. In addition, DC management will perform a review of the Tri-Annual Checklist to ensure it is properly completed. ***New Castle*** DC Management will ensure that exceptions identified in the DEA Tri-annual Checklist are resolved timely.	**Daniel Montreuil** **Blaine Snider**	May 16, 2011 May 16, 2011
21	**ARCOS Count Book** Per the DEA Tri-annual Checklist (reference MOM-CTRL-001) the DCM or designee is required to sign and date the consolidated count book as well as note the time of day the review was performed.	Significance: Low Risk: Lack of proper approval information included on the ARCOS count books may question the integrity and timeliness of the	The DC will ensure that all consolidated ARCOS count books contain the DCM's signature and the required text (date and time of day) to ensure policy compliance.	**Blaine Snider**	May 16, 2011

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	Three consolidated count books at the New Castle DC did not record the time of day in which the count books were approved as required per the checklist. This was previously noted as an exception on the DEA Tri-annual checklist.	controlled substance count approval during a DEA inspection.			
22	**ARCOS Records** Per the DEA Tri-annual Checklist (reference MOM-CTRL-001) controlled substance documents must be maintained in the cage and vault or in a locked file. During our review, we noted the following: *New Castle* Access to the monthly ARCOS boxes, which contain records of controlled substance transactions, was not appropriately restricted. All files (except the current month's working file, which was maintained in a locked filing cabinet) were maintained in an unrestricted location within the warehouse.	Significance: Low Risk: Lack of restricted access to controlled substance documentation may lead to unauthorized personnel accessing sensitive information related to controlled substances.	The DC will properly store all ARCOS records in a locked file or the cage to ensure restricted access as required by policy.	**Blaine Snider**	May 16, 2011
23	**Customer/Consumer Complaints** Per the McKesson Operations Manual (MOM) (Reference MOM-SAF-028), if a consumer or customer of McKesson contacts McKesson to express a complaint regarding any product distributed by McKesson, DC management is to maintain a copy of the written reply to the complainant, as well as a copy of all information sent to the manufacturer. During our review, we noted the following: *Delran* A written reply is not sent responding to customer complaints. Currently, the DC verbally replies to complainants, and a copy or evidence of this reply is not maintained with the record of the customer/consumer complaint. *New Castle* Customer or consumer complaints are not documented on a "complaint record" and no files are created or maintained for the complaint record as required. The DC uses the Oscar application to document customer/consumer complaints.	Significance: Low Risk: Required customer complaint documentation may not be readily available for review, which could result in non-compliance with FDA record keeping requirements.	Management will ensure complaint records are on file for all customer complaints. The Director of Regulatory Affairs will update the associated SOP to ensure it clearly and accurately reflects customer compliant response requirements.	**Tracy Jonas**	May 16, 2011

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	Conroe A written reply is not sent to respond to the complainant nor is a copy of the reply maintained with the record of the customer/consumer complaint as required. Currently, the DC verbally replies customer complaints.				
24	**HAZ Tri-Annual Checklist** Per the McKesson Operations Manual (MOM) (Reference MOM-SAF-21) the HAZ Tri-Annual Checklist will be completed on a tri-annual basis and will be signed and dated by the DCM or higher to attest to its completion. During our review of the HAZ Tri-Annual Checklist at Washington Court House, we noted the following: A) The most recent version of the HAZ Tri-Annual Checklist (HAZ Checklist 02_10_09.xls) was not used by the Distribution Center. The Distribution Center currently uses the Hazardous Materials handling & Transportation Checklist version dated 7/2003. B) DC Management did not indicate the exception that the HAZARDORD3 reports are not reviewed and signed-off as indicated on the HAZ Tri-Annual Checklist.	Significance: Low Risk: Failure to properly complete the required checklist could result in non-compliance with regulatory requirements.	Management will ensure the most recent version of the HAZ Tri-annual Checklist is utilized from the MOM to ensure the DC is compliant with the SOP. In addition, DC management will perform a review of the Tri-Annual Checklist to ensure it is properly completed.	**Kevin Meunier**	May 16, 2011
25	**Hazardous Materials Storage** Per the MOM (Reference MOM-CTRL-001), DC management is required to ensure fully regulated hazardous materials are identified and segregated. In addition, DC management is required to retain hazardous material manifests for a two year period. This is verified by the completion of the Hazardous Material Tri-Annual Checklist to ensure the DC is in compliance with regulatory requirements pertaining to Hazardous Materials and Chemo items. During our review, we noted the following: ***Delran*** The product Nitroling is improperly stored in the Rx section of the warehouse. Nitroling is a flammable product and should be stored in the hazardous materials designated section of the warehouse.	Significance: Low Risk: Inadequate signage and storage of hazardous and chemo products could result in non-compliance with regulatory requirements. In addition, insufficient retention of hazardous material documents could result in non-compliance with regulatory requirements	***Delran*** Hazardous items will be stored in a designated "hazardous material" area that is clearly marked and isolated from non-hazardous product. In addition, DC management will	**Daniel Montreuil**	May 16, 2011

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			ensure the Hazardous Material Tri-Annual Checklist is properly completed and reviewed in order to validate Hazardous Materials are properly segregated and identified.		
	New Castle Hazardous material shipping manifests from calendar year 2010 was not on file, and all shipping manifest from calendar year 2009 had been discarded.		*New Castle* DC Management will ensure the hazardous manifests are retained for the required period of two years.	**Blaine Snider**	May 16, 2011
26	**Hazardous Materials Training** Per the McKesson Operations Manual (MOM) (Reference MOM-SAF-021) training records must be maintained for a period of three years in the safety training files. During our review, we noted the following:	Significance: Low Risk: The lack of sufficient training could result in mishandled product or employees not complying with SOPs or applicable regulatory requirements.			
	New Castle Our review of employee training for hazardous materials noted three employees did not receive training within the three year period. Internal Audit noted training for the three employees last occurred on 12/18/2007.		*New Castle* DC Management will schedule hazardous materials training for all employees handling hazardous materials prior to the employee's certification expiration to ensure training is current. In addition, DC management will monitor employee training records to ensure all required training has been performed.	**Blaine Snider**	May 16, 2011
	Washington Court House During our review of the hazardous material training files, we noted that One of the 13 hazardous material trained employees did not have a copy of the Hazardous Materials Training certificate of completion in their employee file. In addition, we noted that all 13 employees did not receive security training.		*Washington Court House* DC Management will retain hazardous materials training certification of completion for all hazardous material trained employees to ensure the DC is compliant with the SOP. Management will ensure the security training is performed when training for hazardous materials.	**Kevin Meunier**	May 16, 2011
	Conroe One of the 13 hazardous material trained employees did not have a copy of the Hazardous Materials Training certificate of completion in their employee file.		*Conroe* DC Management will retain hazardous materials training certification of completion for all hazardous materials trained employees to ensure the DC is compliant with the SOP.	**Mike Fabela**	May 16, 2011
27	**Hazardous Materials Orders Report** Per the McKesson Operations Manual (MOM) (Reference MOM-SAF-021) a reviewer reviews and signs the	Significance: Low Risk: Failure to properly review the required reports	Management will ensure the HAZARDORD3 reports are reviewed and signed-off by the	**Tracy Jonas**	May 16, 2011

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	CORE_QRY HAZARDORD3 report prior to shipment to verify proper shipment of hazardous orders. During our review at Washington Court House we noted that the HAZARDORD3 reports are printed on a daily basis and filed, however, the reports have never been reviewed and signed by DC management as required per policy.	may result in the mishandling of hazardous materials and possible non-compliance with regulatory requirements.	appropriate hazardous material employee.		
28	**Recall Validation Form** Per the MOM (Reference MOM-RCL-001), recall items must be quarantined upon notification. The number of recalled pieces pulled from each location is required to be recorded in the Acumax system location print screens. Business Reply Cards need to be completed, sent back to the Supplier, and a copy retained. In addition, on a monthly basis, DC management will validate via a random sample that the recall process is operating as directed in the SOP. A "Monthly Recall Validation" form should be printed and attached to the Recall log or folder and completed as directed in the SOP. During our review of the Monthly Recall Validation forms from July and November 2010 we noted the following: ***Delran*** No corrective action was performed for the exceptions identified by DC management on five of the 10 the Monthly Recall Validation forms reviewed. This included a copy of the supplier's business reply card was not located in the recall file and the required number of pieces/lot/expiration date was not recorded to the Acumax print screen. ***New Castle*** No corrective action was performed for the exceptions identified by management on five of the 10 Monthly Recall Validation forms reviewed. The five exceptions included the absence of a copy of the supplier's business reply card in the recall file. In addition, during our review of two recall files Internal Audit noted that management's review did not identify that the number of pieces/lots/expiration dates	Significance: Low Risk: Incomplete documentation and failure to follow established procedures related to recalled product could result in the inappropriate shipment of manufacturer recalled items.	When completing the monthly recall validation form, management will implement a corrective action plan for all exceptions noted on the validation. In addition; all corrective actions will be documented on the Monthly Recall Validation form by DC Management.	**Tracy Jonas**	May 16, 2011

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	were not noted on the Acumax system print screen. ***Washington Court House*** DC management is not completing the Monthly Recall Validation forms as required per policy. Internal Audit noted that the Monthly Recall Validation form was not completed for the months of July and November 2010.				
29	**Expiration Dates** Per the MOM (Reference MOM-SAF-019), the product with the earliest expiration date should be distributed first in order to adhere to the FEFO (First Expired First Out) definition. During our review, we noted the following: ***Delran*** Three out of the 15 inventory locations observed in the warehouse did not conform to the FEFO definition. DC Management noted that on the day Internal Audit performed the inspection, a third party was sanitizing the shelves and improperly returned the products to the shelves. It was noted that the improper return of products was isolated to sections I220 through I222. ***Washington Court House*** Internal Audit noted that four out of the 20 inventory locations observed in the warehouse did not conform to the FEFO definition. ***Conroe*** Two out of the 20 inventory locations observed in the warehouse did not conform to the FEFO definition.	Significance: Low Risk: Older inventory may not be distributed first, which may result in product expiration and inventory required to be removed from the salable inventory.	DC management will ensure older products be placed in the front of the racks for picking in order to adhere to the FEFO method. DC Management will review the SOP with all applicable employees to ensure proper training.	**Tracy Jonas**	May 16, 2011
30	**Cage Access Listing** Per the McKesson Operations Manual (MOM) (Reference MOM-CTRL-001) a list of personnel authorized to enter the cage and vault is posted at both the cage/vault and signed and dated by the DCM. During our review of the cage and vault authorized personnel listing at the Washington Court House DC, Internal Audit noted the date was not notated on the listing indicating the effective date of the authorized	Significance: Low Risk: Unauthorized personnel may be able to access restricted areas storing sensitive products which could result in possible loss or theft of product.	DC Management will ensure that the physical access list (where posted) is updated on a timely basis with DC management signature and effective date.	**Kevin Meunier**	May 16, 2011

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	personnel.				
31	**Note Accounts** Per the McKesson Operations Manual (MOM) (Reference MOM-REG-003), the license fields for "Note" accounts should be listed as "NOTE" within DCUS. Note account types are not an order accounts but are used to flag past due receivables, opening orders, special circumstances (inventory expansion, re-modeling, etc). A review of eight "Note" accounts at the Conroe DC listed on the January Licenses Expiring 12/31/2099 report identified eight that were not updated to include the required verbiage in the license field in accordance with policy requirements.	Significance: Low Risk: Note accounts may not be documented in accordance with policy, which could make it more difficult for the Distribution Center and Accounts Receivable to sort and identify these accounts.	The Sales Admin will review all Note accounts and other accounts that do not require licensure during the review of the 12/31/2099 report. Any inaccuracies identified during that review will be followed up to ensure that those inaccuracies are resolved.	**Mike Fabela**	May 16, 2011
32	**Proof of Delivery For Forms Sent to DEA** Per the McKesson Operations Manual (MOM) (Reference MOM-CTRL-001) Proof of delivery (POD) or "Certified Mail/Return Receipt Requested" should be on file as evidence that the Copy 2 of DEA forms was sent to the local DEA office. During our review of the Washington Court House DC DEA records box, we noted there was no proof of delivery (POD) or "Certified Mail/Return Receipt Requested" on file in the December 2010 DEA box, as evidence that the Copy 2 of DEA 222 forms were sent to local DEA for December 2010. Per ARCOS coordinator, the DC does not have a POD for any of the prior months.	Significance: Low Risk: Lack of documentation on file for controlled substance orders processed may result in the inability to confirm compliance with DEA reporting requirements.	DC Management will ensure that a "Certified Mail/Return Receipt Requested" is on file as evidence that Copy 2 of DEA 222 forms was sent to local DEA.	**Kevin Meunier**	May 16, 2011
33	**222 Forms** Per the McKesson Operations Manual MOM (Reference MOM-CTRL-007), all 222 controlled substance transaction forms are required to be completed and submitted within three business days of the transaction (sale, receipt, credit), so that the information is available for the reporting purposes. Based on our review of controlled substance purchase order forms we noted the following:	Significance: Low Risk: Incomplete or inaccurate controlled substance DEA 222 forms could result in failure to maintain complete and accurate records as required by DEA.	DC management will review procedures for filling out 222 forms with employees to ensure they are current on their responsibilities. In addition, the appropriate level of management will be assigned the task of reviewing and signing the 222 forms to ensure the forms are properly completed.	**Tracy Jonas**	May 16, 2011

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	Delran Ten of the 25 forms selected for testing were not properly completed. This included the lack of adherence to the cancellation process, improper alterations made to the form, absence of a double check stamp, and piece counts that do not reconcile to the total at the bottom of the purchase order. ***New Castle*** Nine of the 25 forms selected for testing were not properly completed. This included the non-adherence to the cancellation process and the absence of a double check stamp. ***Conroe*** A) Inappropriate alterations were made to one of the 25 brown purchase order forms reviewed. B) The return date does not match the DU04 report for one of the 10 returns reviewed.				
34	**Non-Controlled Substances Stored in Controlled Area** Per the McKesson Operations Manual (MOM) (Reference MOM-CTRL-001), if the DC is storing any non-controlled substances and/or "State controlled" substances in the vault or cage a DEA letter of authorization must be obtained authorizing all non-controlled items in the cage/vault. During our review, we noted the following: ***Washington Court House*** Formal DEA approval was not on file for the following non-controlled items stored in the cage: Cialis, Levitra, and Iodine solution.	Significance: Low Risk: Non-controlled substances may be stored in the controlled substances security cage or vault without the appropriate DEA authorization.	Management will contacted the local DEA office for letter granting authorization to store the Levitra Cialis and Iodine solution in the cage. In the interim, a verbal approval has been obtained from the local DEA agent.	**Kevin Meunier**	May 16, 2011
35	**Locker Checks** The McKesson Operations Manual (MOM) (Reference MOM-SEC-002) states that the DC management team is responsible for random door and locker checks and a log of those checks are maintained. This log will provide the names of the mangers that completed the search, the date and the time in which the check was performed.	Significance: Low Risk: Lack of door or locker checks could result in loss or theft product.	Door and locker checks have been included as performance objectives for all managers. Reminders have been set up in outlook to remind each manager a week prior to the end of the month that a random door and locker check needs to be conducted if one has not been already completed.	**Tracy Jonas**	May 16, 2011

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	Based on our review of the door and locker check logs at Washington Court House, we noted that a locker check was not completed for the month of December 2010.				
36	**Computer Room Access List** Per the McKesson Operations Manual (MOM) (Reference MOM-SEC-002) the DC Manager will sign and post a list of people who have badges, keys or access codes to the computer room. The list will be posted outside the room's entrance. The list must be updated anytime a change in staff authorization occurs. The DC is to ensure that the room houses the AS400, security server, telephone server and files server are secured and locked at all times. During our review of Computer Room Access, we noted the following: ***Washington Court House*** Based on our review of the Computer Room Access Listing, we noted one employee was listed on the computer room access list that did not have access to the computer room. ***Conroe*** Using a random sampling of five employees within the DC it was identified that one employee has access to both the computer room and server room but was not on the computer room access list.	Significance: Low Risk: Unauthorized personnel may be able to access restricted areas storing sensitive products and information technology.	Management will ensure that the Computer Room access list is accurately updated on a periodic basis.	**Tracy Jonas**	May 16, 2011
37	**Receiving** The McKesson Operations Manual (MOM) (Reference MOM-SEC-002) requires the receiving stamp to be placed on the bill of lading for orders received, and the stamp should be completed in full. We observed purchase order number 8772843960 being received on 1/19/11 at the New Castle DC. The bill of lading noted a piece count of 60 and it was counted and signed for appropriately. However, the receiving clerk did not complete the following fields on the receiving stamp on the bill of lading: case damaged, cases refused and cases short.	Significance: Low Risk: Items not identified as receiving discrepancies could result in overpayment or negative inventory adjustments.	DC management will review procedures for completing the receiving stamps on the bill of lading forms with receiving employees to ensure they are current on their responsibilities.	**Blaine Snider**	May 16, 2011

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38	**Receiving Discrepancies** Per McKesson Operations Manual (MOM) (Reference MOM-INV-MGT-005) the inventory control personnel will review YRAUD (receiving audit report) in SAP. YRAUD is printed and worked daily, generally by the designated inventory control personnel and/or shipping supervisor. Any differences between the amount received and the amount ordered or the amount received and the amount invoiced are researched. The inventory control personnel and/or shipping supervisor are responsible for filing any necessary e-forms and for documenting carrier/ vendor correspondence (email, fax, and phone) for any missing product to ensure that proper credit is given to the distribution center. The DCIM or their designee signs off the YRAUD report. Ten YRAUD reports selected for testing at the Conroe DC were not signed by the DCIM or designee. There were five of ten instances in which an e-form was filed greater than 48 hours.	Significance: Low Risk: Items not notified as receiving discrepancies could result in overpayment or negative inventory adjustments.	The DC Inventory Manager will sign the SAP generated form on a daily basis. All e-forms will be checked and signed daily by the Assistant DC Inventory Manager to ensure they are filed within 48 hours of receipt.	**Mike Fabela**	May 16, 2011
39	**Receiving Adjustments** The McKesson Operations Manual (MOM) (Reference MOM-RVC-001) states that any purchase order (PO) that has receipts processed against it and has inventory in Acumax available in a unit to adjust, can be adjusted. The only exception is a dock-to-dock PO after the item(s) have been made available in inventory for picking. Only items that have been over received or received in error may be adjusted. Ensure that a cycle count or IAID adjustment has not been previously performed correcting the inventory. For two out of the ten receiving adjustments reviewed at the Conroe DC, a receiving error occurred due to a receiving adjustment being performed after product was put away to a shelf location.	Significance: Low Risk: Inappropriate receiving adjustments could result in a misstatement of inventory.	Continuing education will be performed with all employees who process receiving adjustments to ensure any items that have been put-away to a location are adjusted with IAID and an RACC is performed to offset.	**Mike Fabela**	May 16, 2011
40	**Drop Zone Review** The McKesson Operations Manual (MOM) (Reference MOM-INV-MGT-001) states that on a daily basis, a report of saleable drops zones (DRPZNOLD) is reviewed by the DC and the contents of the drop zones are physically viewed to confirm product on floor matches	Significance: Low Risk: The lack of required report review increases the likelihood of product maintained in Drop Zones for excessive periods, which may	The Allocated Inventory Report will be placed on the job scheduler for once a week and will be reviewed and signed weekly. Continuing education will be given to all employees working the drop zone reports to ensure all	**Mike Fabela**	May 16, 2011

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	the product in the system, and to ensure all items in the drop zones are resolved. Per the put-away SOP, no items should reside in drop zones longer than 48 hours. The Allocated Inventory Report was not reviewed for five weeks selected for testing at the Conroe DC. The DC was performing this control on a monthly basis rather than the weekly requirement. As of January 2011, the Allocated Inventory Report is required to be reviewed and maintained on a weekly basis. In addition, there were four instances in which product were located in a saleable drop zone for more than 4 days.	result in misplaced inventory.	items are cleared and resolved within 48 hours.		
41	**Manual Order Entry** The McKesson Operations Manual (MOM) (Reference MOM-ORD-008) requires the DC to monitor significant price changes made to MOE (manual order entry) orders such as pricing, payment terms and address changes by utilizing the YV_DISCREP_REP transaction in SAP. There were discrepancies with four of the five YV_DISCREP_REP reports reviewed at the Conroe DC: A) One instance in which the DCIM signature was not noted on the report. B) One instance in which a report was retained for review but there was no evidence of review. C) One instance selected in which a customer satisfaction credit was issued utilizing the incorrect credit type. D) One instance reviewed there was no supporting documentation to support the issuance of two customer satisfaction credits.	Significance: Low Risk: Changes to manual order entries may result in inappropriate price changes or shipments sent to an unauthorized address.	The DC Inventory Manager will sign each report on a weekly basis. Continuous Education will be given to all employees who key and release all credit/debits to ensure these are keyed per the SOP. Documentation will be retained with all customer satisfaction credits.	**Mike Fabela**	May 16, 2011
42	**Segregation and Signage for Pedigree Items** The McKesson Operations Manual (MOM) (Reference MOM-PED-GEN-002) mandates that all pedigree items be segregated into unique sections of the warehouse for easy identification. There are different segregated areas of the warehouse based upon the type of pharmaceutical inventory including refrigerated items, controlled substances, and Rx product.	Significance: Low Risk: Pedigree product may not be properly stored in an appropriately labeled pedigree location to ensure the product is shipped with the required documentation and complies with regulatory	Internal Audit validated that all pedigree items were transferred to an appropriately segregated and designated pedigree area. In addition, Internal Audit ensured the proper signage was placed in all areas containing pedigree product.	**Mike Fabela**	Completed

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	Four of the 16 locations in the Conroe DC warehouse containing pedigree product were not appropriately segregated in a designated pedigree area.	requirements.			
43	**Receipt of Damaged Goods** The McKesson Operations Manual (MOM) (Reference MOM-RVC-001) states the DCIM or designee is required to print, review, and sign the DAMGDRECV query daily and retain for a 12 month rolling period. This review is to ensure that follow-up with the vendor is performed for all items with a VDG (Vendor Damaged Goods) and VOD (Vendor Out Date) status code within 48 hours of receipt. The disposition of the item (s) should be clearly defined and included on the query. For one of the ten reports selected for testing at the Conroe DC, Internal Audit noted communication to the vendor for the receipt of damaged inventory was made seven days after the initial receipt.	Significance: Low Risk: Communication to the vendor for damaged product received may not be made in a timely manner, which could result in overpayment and loss of product.	All e-forms will be checked and signed daily by the DC Inventory Manager to ensure they are filed within 48 hours of receipt.	**Mike Fabela**	May 16, 2011
44	**Return Authorizations** Per the McKesson Operations Manual (MOM) (Reference MOM-RET-001) The DCM, DCIM or designee will print and work the suspended credit report on a weekly basis to research and close Return Authorizations suspended for more than five working days. Notes will be added for any pertinent items researched. Copies of the reports will be maintained for 12 months. For one of the ten suspended credit reports selected for testing at the Conroe DC, a return authorization was open for fifteen days.	Significance: Low Risk: Returns may remain suspended or unapproved for excessive periods of time, which could result in misplaced inventory or customer credit not timely issued.	DC Management will ensure that all suspended credits are reviewed and cleared within 5 working days.	**Mike Fabela**	May 16, 2011
45	**Chemotherapy Materials** Per the MOM (Reference MOM-SAF-021), chemotherapy items must be properly labeled, stored, and segregated from other items. During our review at the Conroe DC, we noted that three chemotherapy items were stored in the Rx section of Reclamation instead of the chemo-designated location. In addition, the items were not properly bagged and labeled.	Significance: Low Risk: Inadequate storage of chemo products could result in non-compliance with regulatory requirements.	Management will perform additional training to ensure new employees are aware of all chemo items carried by the DC, and will implement continuing education for all applicable employees.	**Mike Fabela**	May 16, 2011

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
46	**Business Continuity Plan** Per the MOM (Reference MOM-SAF-026), lines of succession, parties in charge of emergencies, and emergency personnel contact information are kept current in the DC's Business Continuity Planning Guidebook. During our review at the Conroe DC, Internal Audit noted that the Listing of Local Incident Management Team and the Medical First Responder/Hazardous Cleanup Team Member list in the DC's Business Continuity Planning Guidebook included a former employee.	Significance: Low Risk: The business continuity plan may not be regularly updated with appropriate contact information and responsibilities, which could impact the DC's response to a crisis affecting operations of the facility.	Information contained in the Business Continuity Planning Guidebook will be updated in a timely manner to ensure vital employees contact information is current and correctly listed.	**Mike Fabela**	May 16, 2011